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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHEN, CATHERYNE	
ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/563,380	BOMBARDELLI ET AL.	
	Examiner	Art Unit	
	Catheryne Chen	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☒ Claim(s) 5, 7, 8 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date Jan. 5, 2006.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, Claims 1-8 are pending.

Claim Objections

The following claims are objected to because of the following informalities: typographical error in Claim 5 for "o"s, Claims 7 and 8 for "benign". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the

art; and the breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to a composition that is able to prevent prostate cancer. In order to be enabled for prevention of a condition, applicant must demonstrate that the invention is able to prevent the condition each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed product is able to prevent prostate cancer for all potential causes of prostate cancer. In addition, the art teaches that prostate cancer prevention is not accepted as possible because many risk factors such as age, race and family history cannot be controlled (see http://www.cancer.org/docroot/CRI/contentCRI_2_4_2X_Can_prostate_cancer_be_prevented_36.asp). Because applicant's specification does not show prevention of prostate cancer and the art acknowledges that prevention is not currently possible, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually functions as claimed. Therefore, the claims are not considered enabled for the prevention of prostate cancer.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-6, 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "compositions" is unclear as to whether

the ingredients are combined because the plural form of composition implies that several combinations of the ingredients are present.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Chopra (US6300377 B1).

Applicant's claim is drawn to a composition comprising of silymarin, lycopene, lauric acid or ester or extract of Serenoa repens or zinc or selenium.

Chopra teaches lauric acid, (column 3, lines 51-53), esters (column 6, lines 50-51, 62-62, 65), zinc, selenium (column 6, line 54), milk thistle extract (column 6, line 57), lycopene (column 6, line 63). Milk thistle extract is known in the arts to encompass silymarin, a mixture of flavonoligans. Thus Milk thistle extract inherently has silymarin.

Claim 1, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Nutricia (EP 1314438 A1).

Applicant's claim is drawn to a composition comprising of silymarin, lycopene, lauric acid or ester or extract of Serenoa repens or zinc or selenium for treating prostate hyperplasia and carcinoma.

Nutricia teaches silymarin (page 3, line 36), zinc (page 3, line 35), saw palmetto (page 3, line 42), selenium (page 3, line 42), lycopene (page 3, 51-52). Saw palmetto is Serenoa repens. Thus extract of Serrenoa repens is the same as saw palmetto extract.

In addition, Nutricia teaches treatment of hyperproliferative cells (page 2, lines 6-7) and for prostate cancer (page 3, lines 5-6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2 rejected under 35 U.S.C. 103(a) as being unpatentable over Chopra (see supra) in view of Gabetta et al. (US 4764508).

Applicant's claim is drawn to a composition comprising of silymarin, lycopene, lauric acid or ester or extract of Serenoa repens or zinc or selenium, where silybin is complexed with phosphatidylcholine.

See Chopra above. However, Chopra does not teach using phospholipids.

Gabetta et al. teaches silybin with phospholipids, specifically phosphatidylcholine (column 2, lines 46-50). The reference does teach that silybin's bioavailability is increased with phospholipids, a known absorption problem particular to silymarin (see column 3, lines 55-59). It would be obvious to complex silymarin with phospholipids to increase its adsorption.

Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that formulating the composition taught by the references in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to formulating the composition taught by the reference in the forms claimed by applicant. It would be obvious to formulate a composition comprising of silymarin with phospholipids in order to increase absorption. Thus, a person of ordinary skill in the art would reasonably expect that silybin complexed with phosphatidylcholine could be used in the composition of the reference.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chopra (see supra) in view of Gabetta et al. (US 4764508) as applied to claims 1-2 above, and further in view of Dietz et al. (US 20001/0046507 A1).

Applicant's claim is drawn to lauric acid methyl or its zinc salt.

Dietz et al. teaches pharmaceutical emulsions comprising of methyl laurate and lycopene (paragraph 0061). Since methyl laurate is a monoester that is suitable for oil components, it can be used as a solvent for lycopene, which is a carotene that is

hydrophobic. The artisan of ordinary skill would reasonably expect that these combinations could be beneficial in the composition taught by Chopra, Gabetta et al., and Dietz et al.

Claim 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chopra (see supra) and Spallholz et al. (US 2003/0083383 A1).

See Chopra discussion above. However, Chopra does not teach particularly methylselenocysteine.

Spallholz et al. teaches methylselenocysteine as a nutriceutical. Methylselenocysteine has been found to be less toxic to normal cells and more toxic to cancer cells than other forms of selenium (paragraph 0019).

Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that formulating the composition taught by the references in the claimed forms would be successful to treat hyperplasia and cancer. Therefore, an artisan of ordinary skill would have been motivated to formulating the composition taught by the reference in the forms claimed by applicant. It would be obvious to formulate a composition comprising of methylselenocysteine with other prostate treatment compositions in order to target prostate hyperplasia and cancer cells. Thus, a person of ordinary skill in the art would reasonably expect that methylselenocysteine with the other compounds could be used in the composition of the reference.

Claims 1, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chopra (see supra) as applied to claim 1 above, and in view of Spallholz et al. (see supra), Corson et al. (see supra), Gabetta et al (see supra), Nutricia (see supra), and Kolodziej et al. (US 2003/0064039 A1).

Applicant's claim is drawn to 100 mg to 1 g of silybin or silymarin or their complexes with phospholipids; 2 to 30 mg of lycopene; 20 to 80 mg of lauric acid or ester of salts thereof; 8 to 16 mg of zinc; 5 to 20 ug of methylselenocysteine.

Applicant's claim is drawn to 160 mg of silybin complexed with phosphatidylcholine; 7.5 mg of lycopene; 22 mg of zinc laurate; 12 ug of methylselenocysteine.

See Chopra discussion above. However, Chopra does not teach, phospholipids, methylselenocysteine, and the different concentrations of the compounds.

Spallholz et al. teaches a dose of 300 ug or less of methylselenocysteine (paragraph 0021). This dosage range would include the claimed range for methylselenocysteine.

Corson et al. teaches milk thistle or silymarin or active compounds of silymarin, such as silybin, at a total dose range of 5 mg to 10 g (column 7, lines 30-35). This dosage range would include the claimed range for silymarin or silybin or equivalent complexes.

Gabetta et al. teaches silybin with phospholipids, specifically phosphatidylcholine, at concentrations at 65.8 mg, 520 mg, 658 mg (column 4, lines 44-

45; column 7, line 380). It would be obvious to include the dose claimed by the applicant for silybin complexed with phosphatidylcholine.

Nutricia teaches lyocpene at 2 mg, 5 mg, 15 mg, 20 mg, 40 mg (page 9, lines 5, 34; page 10, lines 5, 11, 33; page 11. line 13). This dosage range would include the claimed range for lycopene.

Nutricia teaches zinc at 9 mg, 15 mg, 18 mg (page 9, lines 16, 49; page 10, line 38). This dosage range would include the claimed range for zinc.

Kolodziej et al. teaches zinc laurate can be used at 0 to 90% by weight (paragraph 0048). The claimed 22 mg in a total of about 190 mg is about 11% by weight; therefore, it is included in the percentage range for zinc laurate.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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